

Cite No. 2

PCT

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : A61B 5/02, 8/06	A2	(11) International Publication Number: WO 89/07414 (43) International Publication Date: 24 August 1989 (24.08.89)
<p>(21) International Application Number: PCT/GB89/00163</p> <p>(22) International Filing Date: 20 February 1989 (20.02.89)</p> <p>(31) Priority Application Number: 8803840</p> <p>(32) Priority Date: 18 February 1988 (18.02.88)</p> <p>(33) Priority Country: GB</p> <p>(71) Applicant (for JP only): VASCULAR SURGICAL FORUM (GB/GB); Level 7, Bristol Royal Infirmary, Marlborough Street, Bristol BS2 8HW (GB).</p> <p>(72) Inventor; and (73) Inventor/Applicant (for US only): BEARD, Jonathon, David et al. (GB/GB); Department of Surgery, Clinical Science Building, Leicester Royal Infirmary, Leicester LE2 7LX (GB).</p>	<p>(74) Agents: ABRAMS, Michael, John et al.; Haseltine Lake & Co., Hazlitt House, 28 Southampton Buildings, Chancery Lane, London WC2A 1AT (GB).</p> <p>(81) Designated States: JP, US.</p> <p>Published Without international search report and to be republished upon receipt of that report.</p>	
(54) Title: IMPROVEMENTS IN OR RELATING TO MEDICAL APPARATUS AND SURGICAL PROCEDURES		
<p>(57) Abstract</p> <p>Techniques and apparatus of particular value in assessing a patient's suitability for femorodistal by-pass surgery (but also with other applications) are disclosed. In one aspect, a method of testing the vascular condition of a patient comprises applying a pulsatile pressure waveform to a part of the patient's body and observing the resultant blood flow using a non-invasive technique at a location spaced apart from the area of application of said waveform. In another aspect, the method is used to determine the patency of calf arteries in a human or non-human animal, and comprises (a) applying a series of pressure pulses to the exterior of the calf of the animal; and (b) observing blood flow at or near the level of the ankle of the animal by a non-invasive technique. Apparatus provided by the invention comprises: (a) means for applying to the periphery of an area of the animal a pulsatile pressure waveform; and (b) means for observing the blood flow in the animal at a point distal with respect to the application of said pulsatile pressure waveform. An infusor is also disclosed, the infusor comprising a first plunger arranged to act upon a syringe plunger to which the infusor is connected; and a second plunger connected to said first plunger via a compression spring.</p>		

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1 IMPROVEMENTS IN OR RELATING TO MEDICAL APPARATUS AND
 SURGICAL PROCEDURES

 This invention relates to medical apparatus and
surgical procedures which are of particular value in
5 connection with femorodistal by-pass graft procedures.

 The decision to attempt a femorodistal bypass
graft is usually based on the pre-operative demonstration
of an adequate calf vessel runoff. It is an advantage to
know the state of the runoff vessels as this may affect
10 the level of the distal anastomosis and influence graft
patency. When the popliteal artery is occluded it is
essential to detect which calf vessel, if any, is patent
as this will determine whether grafting is at all
possible. Assessment of the pedal arch and its calf
15 vessel connections may also influence the site of the
distal anastomosis.

 The recent upsurge in popularity of femorodistal
grafts for limb salvage has highlighted the shortcomings
of conventional pre-operative arteriography. About
20 one-quarter of crural or pedal arteries that are judged
patent on Doppler ultrasonography or direct operative
exploration may fail to opacify. The use of specialised
techniques such as reactive hyperaemia, vasodilators,
intra-operative arteriography, or digital subtraction
25 arteriography may increase the visualization of distal
vessels but they are not always practicable or available.

 Conventional pre-operative arteriography may fail
to demonstrate patent calf and foot vessels, especially
in the presence of severe ischaemia. Although distal
30 vessels should be judged occluded only if there is
filling of the small collaterals, this may not be
achieved on the initial arteriograms. It may be
uncertain whether failure to demonstrate distal vessels
is due to technical factors or due to occlusion. Repeat
35 arteriograms incur additional expense and delay with no
guarantee of improved definition. Worse still, it may be
assumed that vessels are occluded simply because they

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1 have not been filled with contrast medium, and the patient may thus be denied the chance of reconstruction.

5 Doppler ultrasonography may detect patent crural or pedal vessels that are missed on arteriography but may itself miss patent vessels because of severely damped signals due to a low perfusion pressure. Diligent searching over the area of the vessel without pressure from the probe on the skin and increasing the perfusion pressure by making the feet dependent may help, but
10 require patience and expertise.

An ideal system for assessing distal vessel patency would be non-invasive, safe, simple and rapid to perform. Standard Doppler ultrasound is useful but may also miss patent vessels if signals are severely damped
15 despite a meticulous technique.

A non-invasive method which may be used, inter alia, in determining calf vessel patency has now been developed. This novel method generates blood flow in patent calf arteries by means of a pulsatile cuff located
20 about the calf of a patient. More particularly, according to one aspect of the present invention, there is provided a method of determining the patency of calf arteries in a human or non-human animal, which comprises (a) applying a series of pressure pulses to the exterior
25 of the calf of the animal; and (b) observing blood flow at or near the level of the ankle of the animal by a non-invasive technique.

According to another aspect of the present invention, there is provided a method of testing the
30 vascular condition of a patient, which comprises applying a pulsatile pressure waveform to a part of the patient's body and observing the resultant blood flow using a non-invasive technique at a location spaced apart from the area of application of said waveform.

35 Preferably, the measurement of blood flow at a point distal with respect to the location of the point of application of said pressure pulses is effected by means

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1 of a Doppler velocimeter. Preferably, the pressure
pulses are applied via a cuff which is positioned around
the patient's calf. The pressure pulses are
advantageously produced pneumatically. Preferably the
5 pulsatile pressure waveform has a pulse rate in the range
0.3 - 1.5 pulses per second. A pulse rate of 0.5-1
pulse/second is expected to be satisfactory in most
cases. The magnitude of the pressure pulse preferably is
in the range 150-500 mm Hg. The most advantageous
10 pressure range is 200-300 mm Hg. The applied pressure
may persist for the order of a few milliseconds before it
decays to normal pressure. Such an arrangement can
conveniently be achieved by using a supply of compressed
gas connected to a control arrangement, e.g. a solid
15 state pressure transducer which is used to actuate a
three-way valve; one arm of the valve is connected to the
source of compressed gas, the second arm is connected to
the cuff, and the third arm vents to the atmosphere. The
solid state pressure transducer admits gas from the
20 source to the cuff until the pressure reaches a
predetermined level, at which point the first arm (to the
gas source) is closed and the third arm (which vents to
the atmosphere) is put into communication with the cuff.
When the pressure transducer senses that the cuff
25 pressure has reduced to zero, it closes the vent arm and
re-admits compressed gas to the cuff.

According to a second aspect of the present
invention, there is provided apparatus for use in
assessing the patency of blood vessels in a human or
30 non-human animal, which apparatus comprises: (a) means
for applying to the periphery of an area of the animal a
pulsatile pressure wave form; and (b) means for observing
the blood flow in the animal at a point distal with
respect to the application of said pulsatile pressure
35 wave form. Conveniently, the means for applying said
pulsatile pressure wave form comprises (1) a source of
compressed gas; (2) a pressure control system; and (3) an

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1 inflatable cuff - shaped so as to be locatable about that
area of a patient (e.g. his calf) which is to be
investigated. The pressure control system is preferably
in the form of a pressure transducer which actuates a
5 three-way valve, whereby compressed gas is admitted to
the inflatable cuff until a predetermined pressure
cut-off point is reached, whereupon the pressure
transducer stops the supply of compressed gas and vents
the interior of the inflatable cuff to the atmosphere;
10 when the pressure within the inflatable cuff falls to
zero (gauge), the pressure transducer closes the vent
port and re-admits compressed gas to the inflatable cuff.
This cycle is repeated generating thereby the pulsatile
pressure wave form.

15 Blood flow at the distal location is preferably
detected by a Doppler ultrasound technique. A
conventional Doppler velocimeter (e.g. operating in the
range 2 to 12 MHz) may be used for this purpose.

The apparatus and techniques described above are
20 particularly valuable in assessing whether or not to
perform a femorodistal bypass graft. If a decision to
undertake this procedure is taken, it is still necessary
to monitor the peripheral resistance of runoff at the
beginning of the surgical procedure in order to give a
25 more confident physiological test of runoff and to
correlate with subsequent graft patency. Present methods
of peripheral resistance measurement, however, are
cumbersome and not well suited for clinical use.

Despite recent advances such as the use of the in
30 situ vein technique, about one third of all femorodistal
bypass grafts performed for critical ischaemia occlude
within the first year, the majority within the first
month. A failed graft is extremely costly in terms of
increased patient morbidity, prolonged hospital stay and
35 wasted operating time.

Continued graft patency is determined by an
adequate blood flow which is largely dependent upon the

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1 state of the distal runoff vessels. Pre-operative
assessment is usually based upon a combination of
non-invasive Doppler ankle pressures and arteriography
which give little functional information and may miss
5 patent calf vessels. Measurement of the peripheral
resistance at the start of the operation has recently
been claimed to provide more functional information about
the runoff than is available pre-operatively.

The methods described heretofore in the literature
10 all measure the peripheral resistance by recording the
pressure generated by a constant flow of saline or blood
infused into the runoff vessels. These constant-flow
systems are difficult to use and time-consuming to set
up. Furthermore, the constant-flow system does not
15 correlate with natural blood flow, which varies in flow
rate but more closely approximates to constant pressure
flow conditions. Accordingly, another objective of the
present invention was to develop a simple
constant-pressure method for measuring the peripheral
20 resistance at the start of operation.

According to a further aspect of the present
invention, there is provided an infusor suitable for use
in measuring peripheral resistance, which infusor
comprises a first plunger arranged to act upon a syringe
25 plunger to which the infusor is connected; and a second
plunger connected to said first plunger via a compression
spring. The second plunger conveniently nests into the
interior of a cylindrical shaft which constitutes an
extension of the first plunger; the end of said hollow
30 cylindrical shaft can then function as a marker against a
scale graduated on the cylindrical surface of the second
plunger.

In use, a surgeon will connect the infusor to a
disposable syringe which contains the liquid which is to
35 be injected (preferably blood or saline), and will then
use the infusor to inject the liquid into a distal artery
under constant pressure conditions. This is monitored by

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1 maintaining a fixed relationship between the ends of the
first and second plungers ~ this being readily indicated
by the position of the end of the first plunger against
the graduated scale provided on the shaft of the second
5 plunger.

For a better understanding of the invention, and
to show how the same may be carried into effect,
reference will now be made, by way of example, to the
accompanying drawings, in which:

10 FIGURE 1 illustrates the application of the
invention to assessment of calf vessel patency;

FIGURE 2 illustrates the pulsatile blood flow as
observed by a Doppler velocimeter in the course of an
assessment using the apparatus and techniques of this
15 invention;

FIGURE 3 is a plot showing the correlation between
calf vessel patency as determined in accordance with the
present invention on the one hand and as determined by
arteriography on the other hand;

20 FIGURE 4 is a plot of the peripheral resistance of
calf vessels against the assessment of calf vessel
patency as determined using apparatus and techniques in
accordance with the invention;

FIGURE 5 is an illustration of an infusor in
25 accordance with the invention;

FIGURE 6 is a plot of the pre-operative
arteriogram score against the measurement of peripheral
resistance at the start of the operation using the
infusor of Fig. 5;

30 FIGURE 7 is a plot of the peripheral resistance
measurements versus success or failure of the
femoro-distal by pass grafts at one month after the
operation;

FIGURE 8 is a diagram showing the pneumatic
35 circuitry in one embodiment of this invention; and

FIGURE 9 is a logic circuit corresponding to the
pneumatic circuitry of Figure 8.

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1 In one preferred embodiment, the present invention
uses a standard 10 MHz Doppler ultrasound velocimeter and
a sphygmomanometer cuff driven by pulsatile compressed
air. The cuff is placed around the upper calf and the
5 pulsatile pressure generates blood flow in the calf
arteries. Patent arteries can be detected by the Doppler
probe at the ankle even if the existing signal is
inaudible. The pedal arch patency test is also easily
performed to determine continuity with the pedal arch.
10 An occlusive thigh cuff is occasionally required to
prevent interference by the normal arterial signal
although it is not usually necessary in severely
ischaemic limbs. Venous signals are readily
differentiated from arterial ones as they are
15 characteristically attenuated by the venous valves which
prevented retrograde flow. Theoretically there might be
a problem in patients with deep venous incompetence but
this has not been encountered clinically.

Referring to Figure 1, there is shown
20 schematically the arrangement adopted in utilising the
PGR system described above. An inflatable cuff 1 is
positioned around the patient's calf. A pulsatile
pressure waveform is applied by the cuff which is fed
with compressed air via a control arrangement (not shown)
25 and supply tube 2. The pressure waveform is depicted
schematically at 3. Blood flow in the runoff vessels is
determined using a conventional Doppler velocimeter 4
which is held in contact with the patient's limb in the
ankle region in order to detect blood flow in one of the
30 three runoff arteries. The output of the Doppler
velocimeter is illustrated at 5 (showing the signal
obtained where runoff is adequate). A further cuff 6 is
shown located about the patient's thigh; this functions
as a conventional sphygmomanometer cuff and is required
35 only where the normal arterial signal would interfere
with that deriving from the PGR system - i.e. in patients
with relatively little ischaemia.

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1 The control unit is driven by compressed air and
consists of two separate modules controlling the
pulsatile and occlusive cuffs. The inflation and
deflation of the pulsatile cuff is controlled by a
5 two-way solenoid valve and an in-line solid-state
pressure transducer. The pulse pressure can be varied
from 0 to 300 mm Hg and the frequency of pulsation from 0
to 100/min but a standard pulse of 250 mm Hg at a rate of
50/min is usually used. The occlusive cuff pressure is
10 controlled by a standard pressure regulator and can be
varied from 0 to 300 mm Hg. For convenience, the system
just described above is termed herein "pulse generated
runoff" or "PGR".

Figures 8 and 9 illustrate circuitry used in one
15 embodiment of apparatus in accordance with this
invention. Conventional symbols are used in the two
circuits to denote conventional components as will be
recognised by those skilled in the art of pneumatics.
The upper part of the circuit of Figure 8 functions as a
20 timer circuit which produces a pulse to a cuff
inflate/deflate valve 30. The time in which the cuff is
inflated and deflated can be adjusted by means of two
throttle valves 31 and 32. The system is activated by a
foot actuator 33 connected into the timer circuit in such
25 a way that it can stop a pressure pulse activating the
cuff inflate/deflate valve 30. The pressure pulse is fed
to valve 30 via a two way toggle valve 34 which acts as
an emergency deflate valve. Valve 30 is connected to the
cuff 35 for inflation/deflation thereof. Deflation of
30 the cuff takes place straight through valve 30 to exhaust
without any throttle since it is desirable for deflation
to occur as rapidly as possible. The remainder of the
pneumatic circuit comprises a throttle 36 and a cuff
supply regulator 37.

35 The logic circuit of Figure 9 corresponds to the
pneumatic circuit of Figure 8 except that there is no
emergency deflate valve 34, and there are two

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- 1 inflate/deflate valves 30, 30a in order to provide an
increased volume of air to the cuff 35.

Using the PGR system a search was made in a series
of human patients for all three calf vessels at the level
5 of the ankle (anterior tibial, posterior tibial and
peroneal arteries). Each vessel was scored 2 for a
normal biphasic signal; 1 for a damped monophasic signal
and 0 for no signal, giving a possible total of 0-6. A
normal signal has a sharp upstroke as the cuff inflates,
10 an amplitude >2cm and reversed flow as the cuff deflates
(Figure 2).

Pre-operative arteriograms also carried out on the
same group of patients, and were were scored at a weekly
meeting of the consultant vascular surgeons and
15 radiologists. Each calf vessel was scored 2 if patent to
the ankle, 1 if patent but diseased and 0 if occluded,
again giving a possible total of 0-6. Arteriograms were
judged to be inadequate if there was no filling of calf
collaterals on any of the series. Assessment of the
20 plantar arch proved to be impossible because it was
rarely adequately demonstrated.

Ninety-five ischaemic limbs with superficial
femoral artery occlusion were studied in 76 patients (49
men and 27 women, aged 42-92 years, median 76 years). Of
25 these limbs, 68 were critically ischaemic with rest pain
and/or gangrene and 27 had symptoms of claudication only.
All patients underwent transfemoral aortography except
for six who had unilateral femoral arteriograms.
Pulse-generated runoff (PGR) assessments were made on all
30 limbs within 24 h of arteriography.

Ten control limbs were studied in five patients
with isolated aortoiliac disease, whose arteriograms
demonstrated three patent calf vessels down to the ankle.

The peripheral resistance was measured in all of
35 the 62 limbs undergoing femorodistal reconstruction or
amputation. Of the 62 limbs, 9 received a primary
amputation based upon the pre-operative arteriogram and

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1 the degree of tissue loss. The remaining re-underwent
exploration with a view to reconstruction, and of these,
5 received a below-knee amputation, the other 48
receiving an in situ femorodistal vein graft. The
5 decision to amputate was made by the consultant surgeon
if the distal vessels were occluded or severely diseased.
The distal anastomosis was to the infrageniculate
popliteal in 29 limbs, the tibioperoneal trunk in 10 and
to a calf vessel in 9 limbs.

10 The peripheral resistance was measured by a method
similar to that described by Parvin (Br J Surg 1985; 72;
751-3). An infusion of heparinised blood was made by
hand, via a soft 6 or 8 French PVC catheter inserted
through an arteriotomy into the vessel chosen for the
15 distal anastomosis. The resistance was calculated from
the simultaneously recorded pressure and flow, a
deduction being made for the resistance of the catheter.
The resistance in the primary amputation group was
measured in the calf vessel thought best on exploration
20 before amputation. The results obtained are described
below.

The 10 control limbs with arteriogram scores of 6
all scored 6 on the PGR assessment. Seventeen
arteriograms (18 per cent) were judged inadequate for
25 scoring leaving seventy-eight for comparison with the PGR
(Figure 3). There was a highly significant correlation
between the arteriogram and the PGR scores (Spearman's
Rank Correlation, 0.74; $P < 0.001$). In severely ischaemic
limbs the PGR tended to detect more vessels than
30 arteriography, detecting at least one patent vessel in
eight limbs (8 per cent) where no vessel was judged
patent and in sixteen limbs (17 per cent) where the
arteriogram was judged inadequate.

The peripheral resistance, measured in the 62
35 operated limbs, correlated better with the PGR than the
arteriogram score (Figure 4) although both were highly
significant (Spearman's Rank Correlation, -0.71 and -0.54

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1 respectively; $P < 0.001$). There was a highly significant
difference between the peripheral resistance of amputated
limbs and those undergoing femorodistal bypass
(Mann-Whitney U test, $P = 0.0001$). Three of the primary
5 amputations had resistances which would have been
compatible with reconstruction. No vessels were detected
by pre-operative arteriography or conventional Doppler
examination but the PGR system demonstrated at least one
patent vessel in all three of these limbs.

10 It was initially thought that the PGR system
worked by direct compression of the popliteal and calf
arteries. However, satisfactory signals were obtained on
diabetic limbs with heavily calcified incompressible
vessels. This suggests that compression of the calf
15 muscles was the source, the blood flowing retrogradely
into the calf arteries. Patients did not find the
pulsatile cuff unduly uncomfortable and no problems of
increased ischaemia due to arterial damage were
encountered.

20 The use of the pulse-generated runoff (PGR) system
in accordance with this invention means that the distal
vessels can be assessed independently of any proximal
disease. Detection of patent vessels in the calf or foot
is quickly and easily performed because of the enhanced
25 flow signals.

The PGR system described above is inexpensive to
construct and can be used with any available Doppler
velocimeter. PGR correlates significantly with the
pre-operative arteriogram score but in severely ischaemic
30 limbs may detect up to 25 per cent more patent vessels.
There is a better correlation between the peripheral
resistance and PGR than the arteriogram score, suggesting
that PGR is a more physiological test of runoff.
Pre-operative arteriography usually shows the popliteal
35 and upper calf vessels sufficiently well to indicate the
necessary level of bypass. PGR is able to confirm the

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1 patency of the distal calf and foot vessels and helps to determine the best vessel for exploration.

Although described above in relation to the assessment of arterial patency in the calf, the present invention may also be used inter alia to assess the condition of veins. For example, in healthy veins, the venous valves will prevent retrograde blood flow; hence if a Doppler velocimeter is used to assess venous flow in the technique described above, the Doppler signal will indicate whether or not there is deep venous incompetence. This condition will allow retrograde blood flow and thus will give a Doppler signal somewhat resembling that obtained with arterial measurements as described above. Where the deep veins are in a healthy condition, the Doppler signal will be strongly damped indicating the closure of the venous valves and resultant lack of retrograde blood flow.

The invention may also be used to assess the condition of the long saphenous vein prior to its use in femorodistal bypass graft surgery. If the vein is in poor condition, this will be evident as a result of examination by the technique and with the apparatus of this invention.

Furthermore, the pulsatile wave form applied by the method of this invention to a body part may be used to generate a signal from a distal blood vessel which signal is then subjected to data processing so that the invention is used to generate a transmission line analysis for blood vessels located between the point of application of the pressure wave form and the point at which blood flow measurements are taken. In this embodiment, the pulsatile pressure wave form may have a higher frequency than that used in arterial and venous assessment.

35 In the embodiments described above, the inflatable cuff should be of a size adequate to compress muscle within the body part about which the cuff is located.

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1 Where the pressure is derived from compressed air, the connections (e.g. tubing) between the compressed gas source and the inflatable cuff should be of wide bore in order to prevent undue pressure loss and/or pulse delays.

5 A preferred embodiment of an infusor in accordance with this invention and its use in surgical procedures will now be described in greater detail with reference to Figures 5 - 7 of the drawings.

Referring first to Fig. 5, an infusor 20 is shown attached to a conventional disposable syringe 21. The infusor comprises a body portion 22 which carries on its exterior surface a correlation table 23 which relates the time taken to effect an infusion (in seconds) with the peripheral resistance of the runoff. Within body portion 22 there are two concentric plungers. The first plunger acts upon the syringe 21. The distal end 24 of the first plunger includes a slot 25 which receives a pin 26 carried by the shaft 27 of the second plunger. A pressure scale 28 is provided on the side of shaft 27. Within the body of the infusor, there is a compression spring which links the action of the first and second plungers so that, under constant pressure infusion conditions, the depth of penetration of shaft 27 into the interior of part 24 of the first plunger remains constant. This is indicated by alignment of the end 29 of part 24 with the scale 28.

The plungers of the infusor shown in Fig. 5 were made of stainless steel for ease of cleaning and sterilization.

30 At the start of operation the artery selected for the distal anastomosis (infra-geniculate popliteal or crural) was exposed and a longitudinal arteriotomy performed. An infusion of heparinized blood, at a constant pressure of 100 mmHg, was then made by hand via a soft 6 or 8 French PVC catheter (Portex) inserted into the distal vessel (Fig. 2). The patient's own blood was used for peripheral resistance measurements and was

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- 1 usually obtained from the femoral artery. A series of
three infusions were made and the total resistance
calculated from a simple nomogram which converted the
time taken to infuse 20 ml blood into peripheral
5 resistance units (PRU):

$$\text{where } 1 \text{ PRU} = \frac{1 \text{ mmHg blood pressure}}{1 \text{ ml/min blood flow}}$$

- The lowest of the 3 measurements was used to calculate
10 the peripheral resistance (R_p) by subtracting the
catheter resistance (R_c) from the total resistance (R_T):

$$\text{where } R_p = R_T - R_c$$

- 15 The catheter resistance was determined by infusing blood
through the catheter into a small bowl. The resistances
of the 6 and 8 French catheters were about 1.75 and 0.55
PRU respectively.

- Peripheral resistance measurements were made at
20 the start of 47 in situ vein femorodistal bypass grafts
performed for critical ischaemia. All patients underwent
preoperative transfemoral arteriography. The anterior
tibial, posterior tibial and peroneal arteries were
scored at a joint weekly meeting of the consultant
25 vascular surgeons and radiologists. Each vessel was
awarded 2 points if patent from the level of the distal
anastomosis to the ankle, 1 point if patent but diseased
and 0 if occluded giving a possible total of 0 to 6. The
pedal circulation was often inadequately demonstrated and
30 was not included in the scoring system.

- Once the graft was completed the peripheral
resistance was calculated from the graft blood flow and
pressure using a newly developed Doppler flowmeter and a
Gould pressure transducer. A graft was considered to be
35 successful at 1 month if it was patent on duplex
ultrasound scanning with a rise in the postoperative

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- 1 Doppler ankle/brachial pressure index (ABPI) of >0.25 and
a clinical improvement.

The 1 month primary failure rate was 12 out of 47
(26%). The 12 failures included 8 grafts which occluded
5 between 12 hours and 15 days postoperatively and 4 grafts
which although patent, resulted in no improvement
clinically or in the ABPI. The above-knees amputation
rate for these failures was 55%.

The preoperative arteriograms were judged
10 inadequate for scoring purposes in 9 cases (19%). There
was a good correlation between the preoperative
arteriogram score and the peripheral resistance measured
at the start of operation with the constant-pressure
infusor of Fig. 5 (Spearman's rank correlation), $r_s=0.85$,
15 and this correlation is shown in Figure 6). The
peripheral resistance measured with the constant-pressure
infusor correlated better than the arteriogram score with
the peripheral resistance measured once the graft was
completed (Spearman's rank correlation, $r_s=0.97$ and 0.86
20 respectively, show in Fig. 7).

There was a highly significant difference between
the peripheral resistances, measured with the
constant-pressure infusor, of grafts that were successful
and those that failed at 1 month (Mann Whitney U test,
25 $p=0.0008$). A peripheral resistance >2 PRU predicted
early graft failure in 8 out of 12 cases (sensitivity 67%
and specificity 89%). Although there was a significant
difference between the arteriogram scores of successful
and failed grafts (Mann Whitney U test, $p=0.01$), the
30 predictive value was lower (sensitivity 55% and
specificity 72%).

Measurement of the peripheral resistance by an
infusion of saline or blood at the start of the operation
is a more physiological method of assessing the runoff.
35 Constant-flow systems may result in excessive pressure
being generated if the peripheral resistance is high.
This may lead to endothelial damage and falsely lower the

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1 resistance because of overdistension of the arterial
system. Constant-flow systems are also expensive because
of the pumps required and time-consuming to set up.

5 The constant-pressure infusor avoided the risk of
overdistending the arterial system. It was also more
physiological as the cardiovascular system depends upon a
constant pressure rather than a constant flow. The
constant-pressure infusor was simple to construct and
easy to sterilize as it used disposable syringes. Blood
10 rather than saline was used for the resistance
measurements to avoid the need to make a correction for
viscosity. Glass syringes have also been used. These
have the advantage of lower friction than disposable
syringes but require cleaning and sterilization.

15 The results confirm the findings of previous
studies that measurement of the peripheral resistance
before proceeding to femorodistal bypass gives more
information about the runoff than preoperative
arteriography. In this study a peripheral resistance of
20 >2 PRU was associated with a very high incidence of
subsequent graft failure.

Measurement of the peripheral resistance using the
infusor may also have other areas of application in
peripheral and coronary artery surgery. Its use after
25 arterial embolectomy might indicate whether a successful
outcome was likely or not, thus enabling other measures
to be taken if necessary, e.g. thrombolytic therapy. In
coronary artery bypass surgery it would be an advantage
to have some indication of the likely success of a graft
30 during the period of cardioplegia.

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1 CLAIMS:

1. A method of testing the vascular condition of a patient, which comprises applying a pulsatile pressure waveform to a part of the patient's body and observing the resultant blood flow using a non-invasive technique at a location spaced apart from the area of application of said waveform.

2. A method of determining the patency of calf arteries in a human or non-human animal, which comprises (a) applying a series of pressure pulses to the exterior of the calf of the animal; and (b) observing blood flow at or near the level of the ankle of the animal by a non-invasive technique.

3. A method as claimed in claim 1 or 2, wherein blood flow at said distal location is observed by means of Doppler ultrasonography.

4. A method as claimed in claim 1, 2 or 3, wherein said pressure pulses are generated pneumatically.

5. A method as claimed in claim 1, 2, 3 or 4, wherein said pressure pulses have a pulse rate in the range 0.3 - 1.5 pulses per second.

6. A method as claimed in claim 3, wherein said pressure pulses have a pulse rate in the range 0.5 - 1.0 pulses per second.

7. A method as claimed in claim 1, 2, 3 or 4, wherein said pressure pulses have a maximum pressure in the range 150-500 mm Hg (gauge).

8. A method as claimed in claim 7, wherein said pressure pulses have a maximum pressure in the range 200-300 mm Hg (gauge).

9. Apparatus for use in assessing the patency of blood vessels in a human or non-human animal, which apparatus comprises: (a) means for applying to the periphery of an area of the animal a pulsatile pressure wave form; and (b) means for observing the blood flow in

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1 the animal at a point distal with respect to the application of said pulsatile pressure wave form.

10. Apparatus as claimed in claim 9, wherein said means for applying to the periphery of an area of the
5 animal a pulsatile pressure wave form comprises an inflatable cuff.

11. Apparatus as claimed in claim 10, wherein said inflatable cuff is a sphygmomanometer cuff.

12. Apparatus as claimed in claim 10 or 11,
10 wherein said pressure control system is in the form of a pressure transducer which is arranged to actuate a three-way valve, whereby in use compressed gas is admitted to the inflatable cuff until a predetermined pressure cut-off point is reached, whereupon the pressure
15 transducer stops the supply of compressed gas and vents the interior of the inflatable cuff to the atmosphere.

13. An infusor suitable for use in measuring peripheral resistance, which infusor comprises a first plunger arranged to act upon a syringe plunger to which
20 the infusor is connected; and a second plunger connected to said first plunger via a compression spring.

14. An infusor as claimed in claim 13, wherein said second plunger is arranged to nest into the interior of a cylindrical shaft which constitutes an extension of
25 said first plunger.

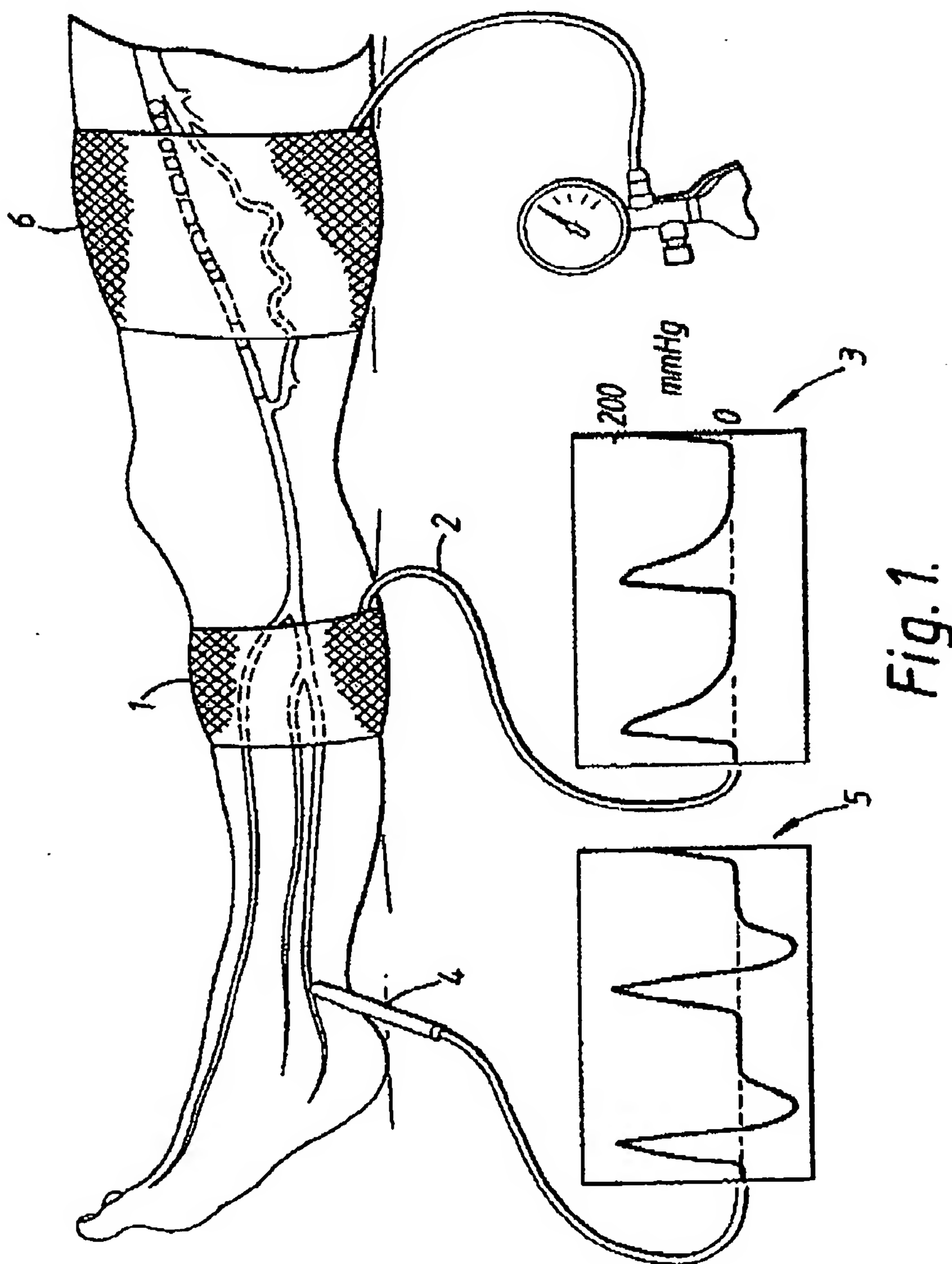
15. An infusor as claimed in claim 14, wherein the end of said hollow cylindrical shaft is arranged to function as a marker against a scale graduated on the cylindrical surface of the second plunger.
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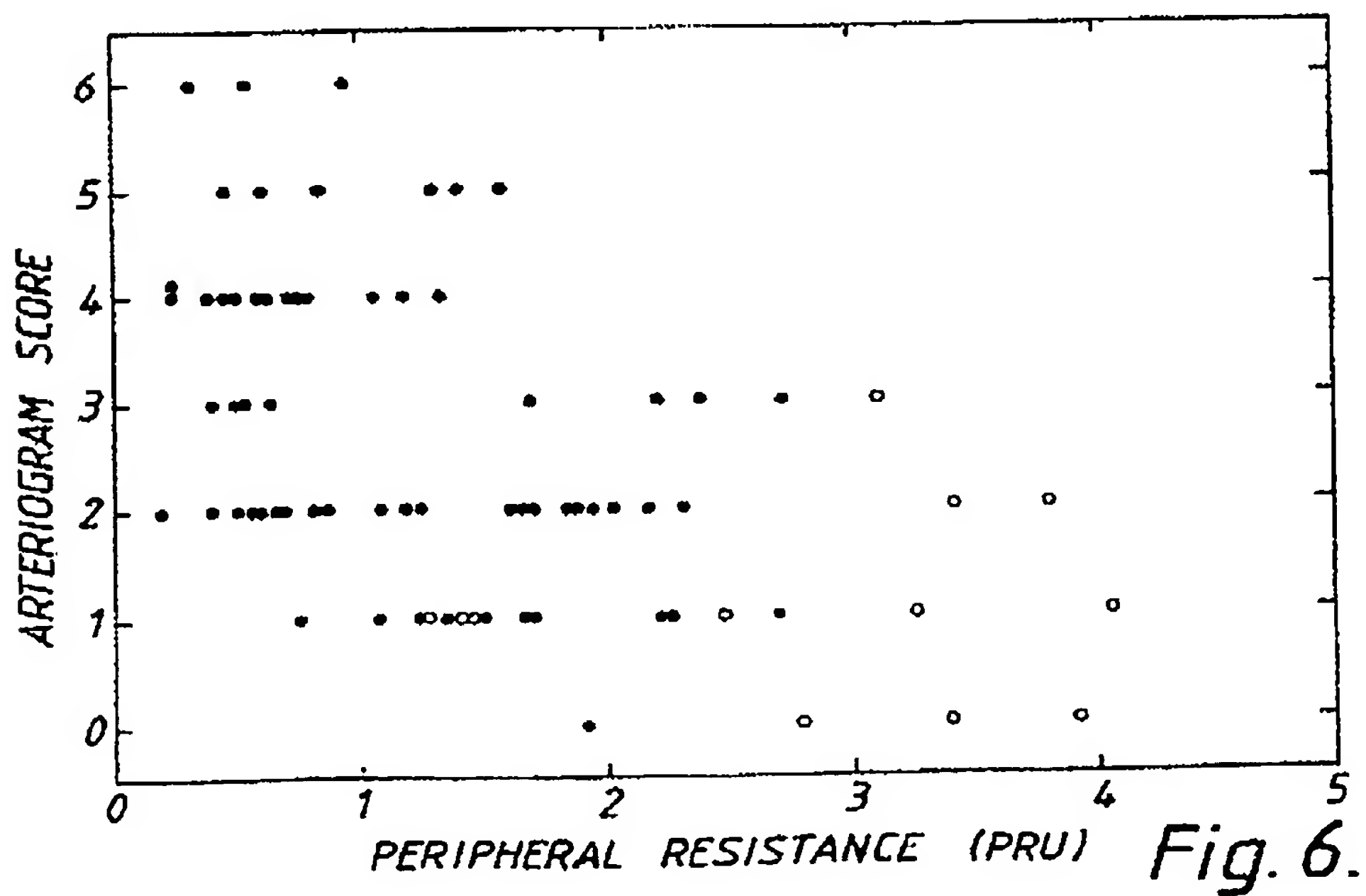
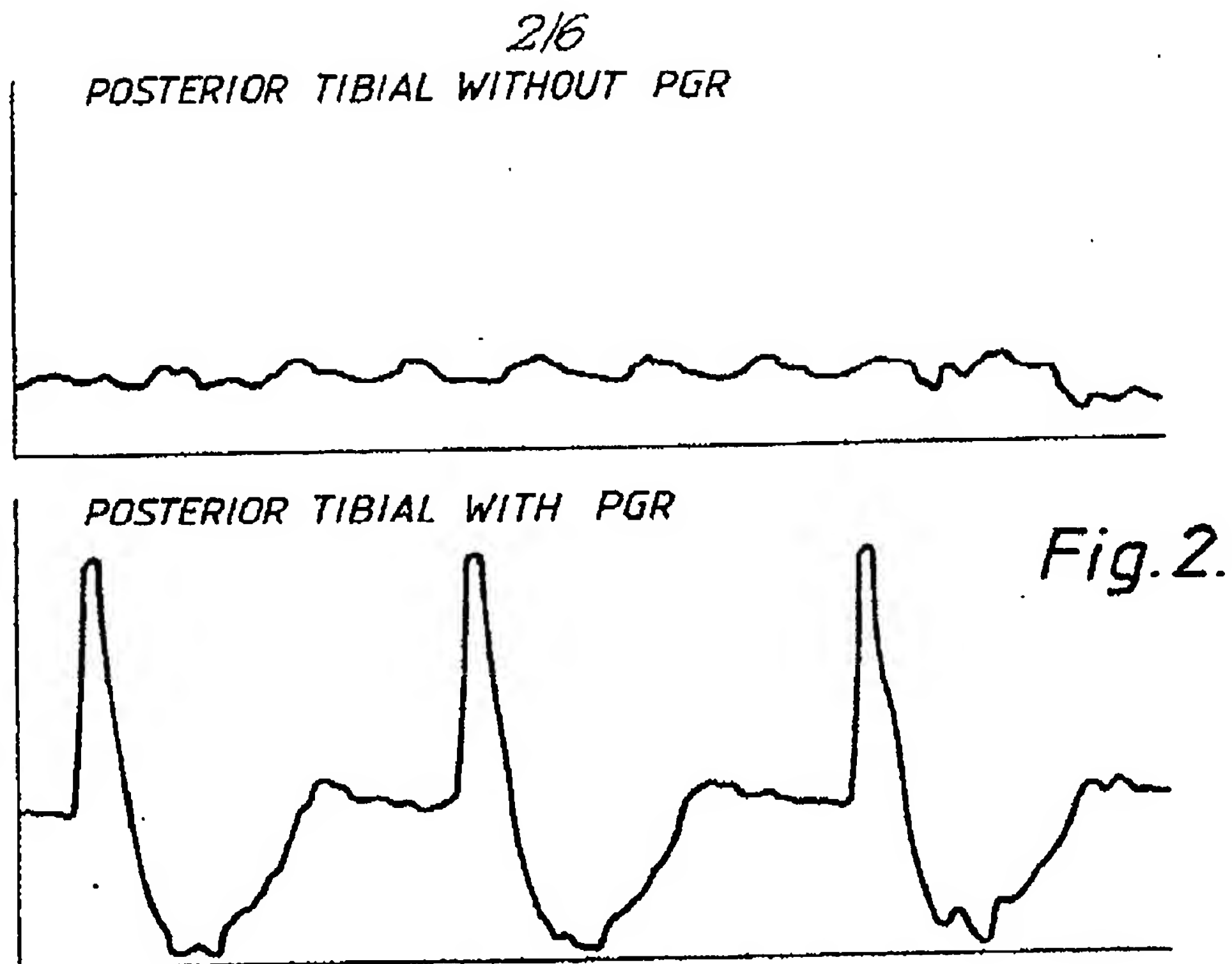
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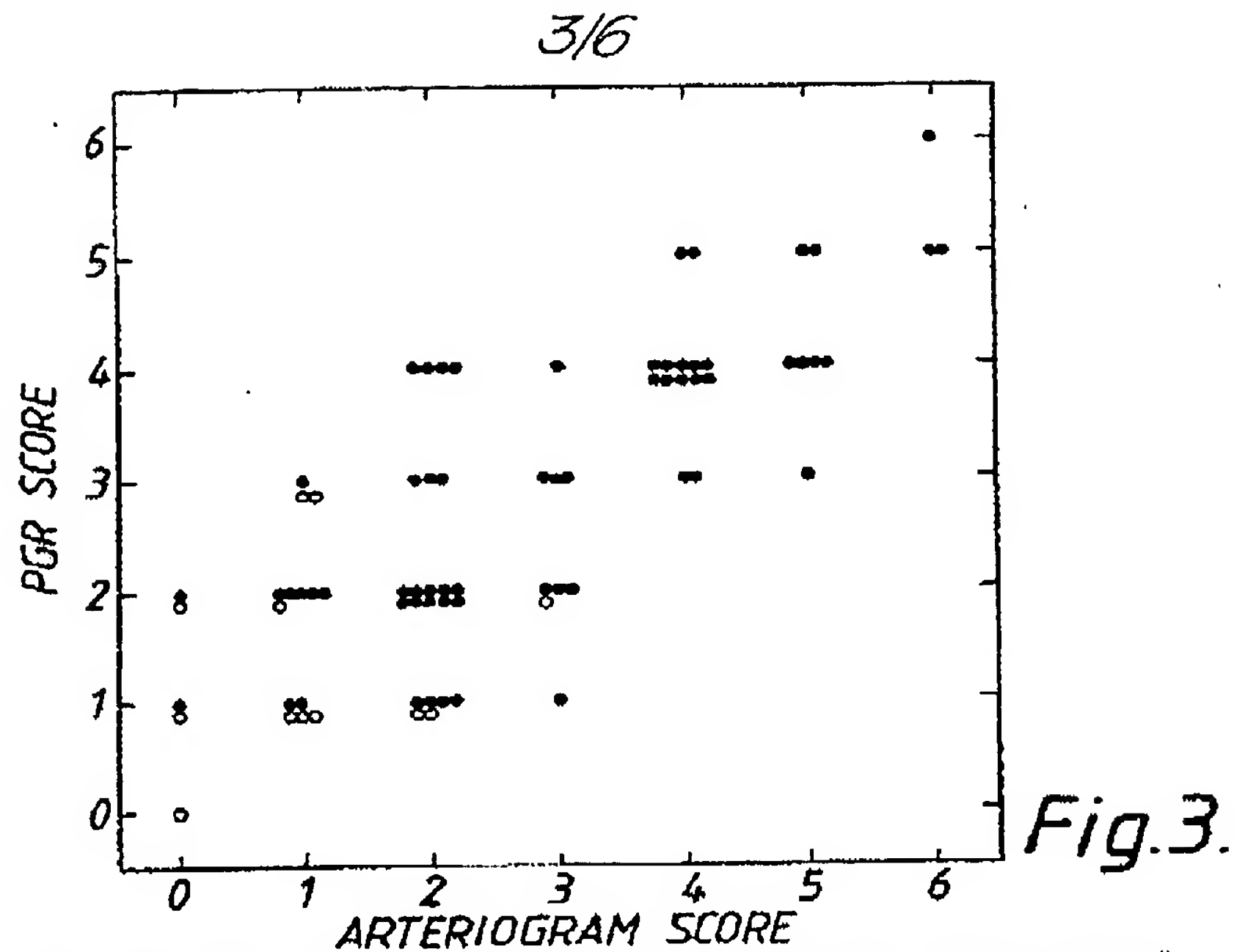
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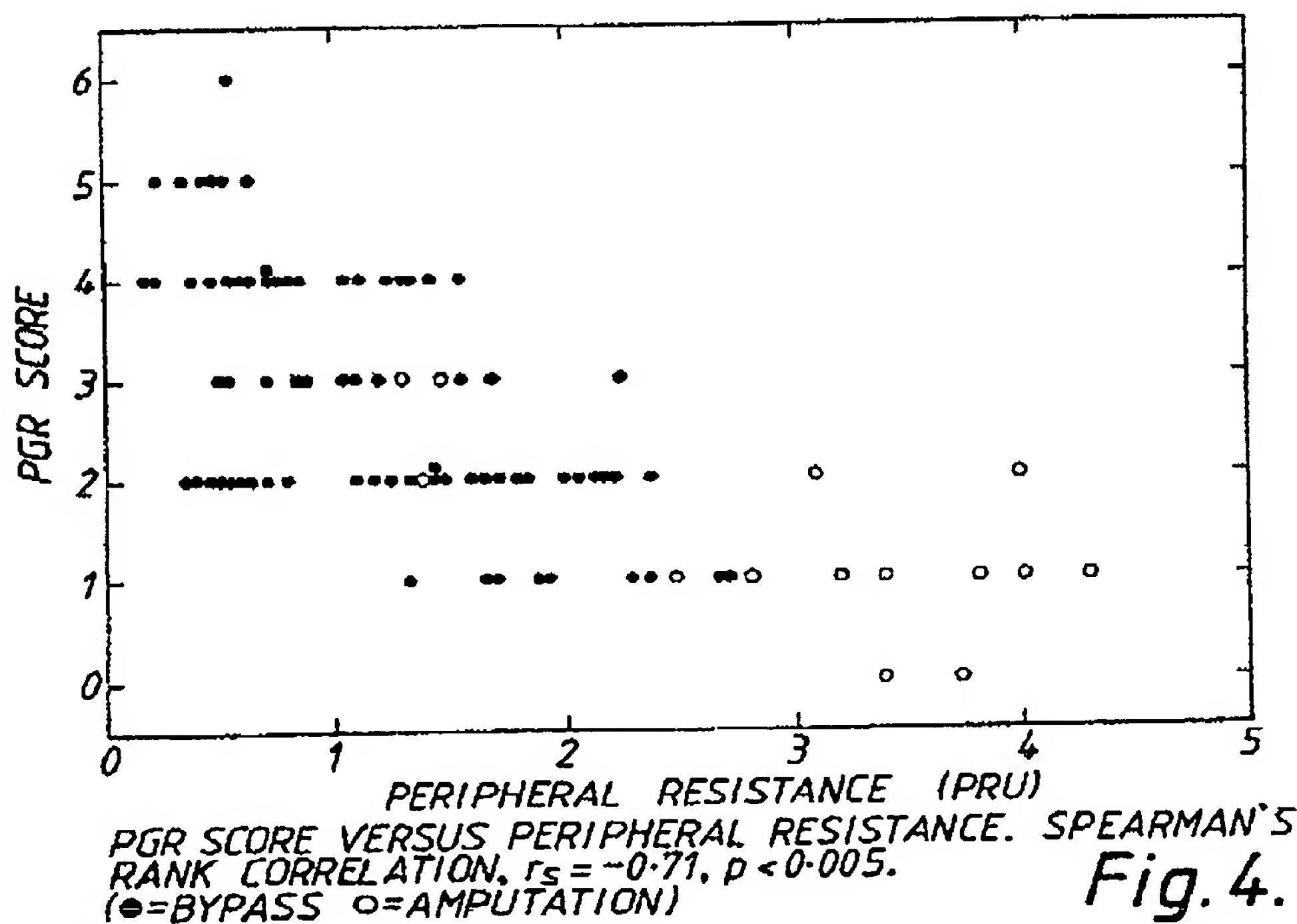


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PREOPERATIVE ARTERIOGRAM SCORE VERSUS PGR SCORE.
SPEARMAN'S RANK CORRELATION, $r_s = 0.73$ $p < 0.005$.
(●=BYPASS, ○=AMPUTATION)



PGR SCORE VERSUS PERIPHERAL RESISTANCE. SPEARMAN'S
RANK CORRELATION, $r_s = -0.71$, $p < 0.005$.
(●=BYPASS ○=AMPUTATION)

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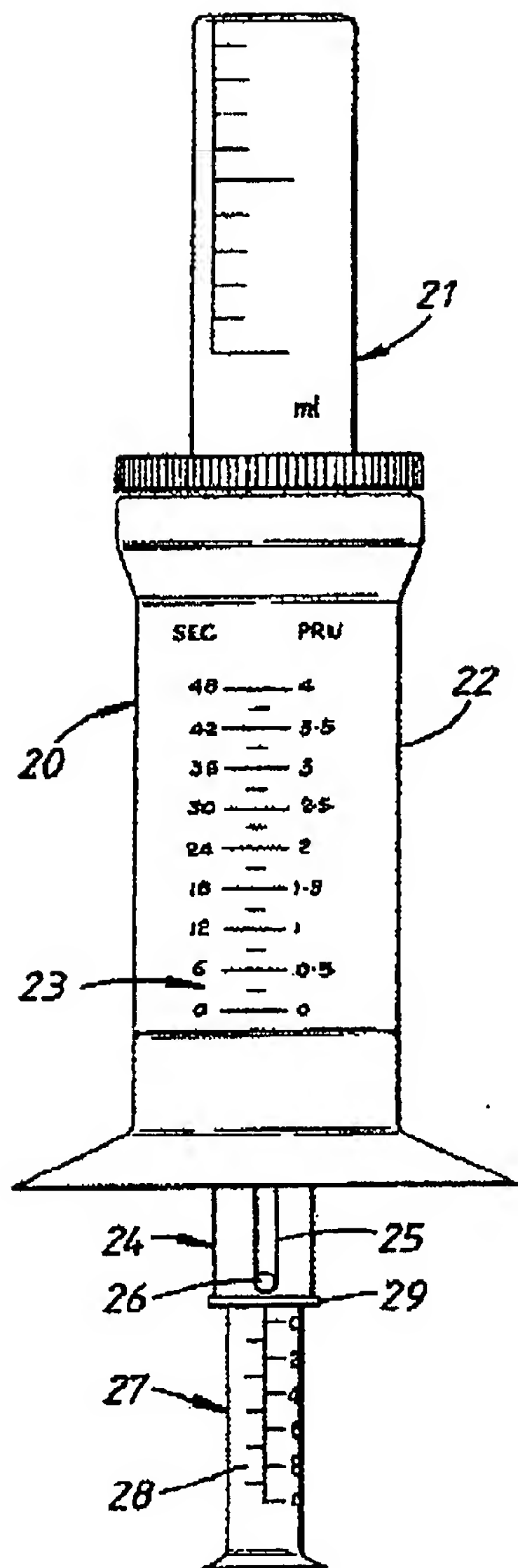


Fig. 5.

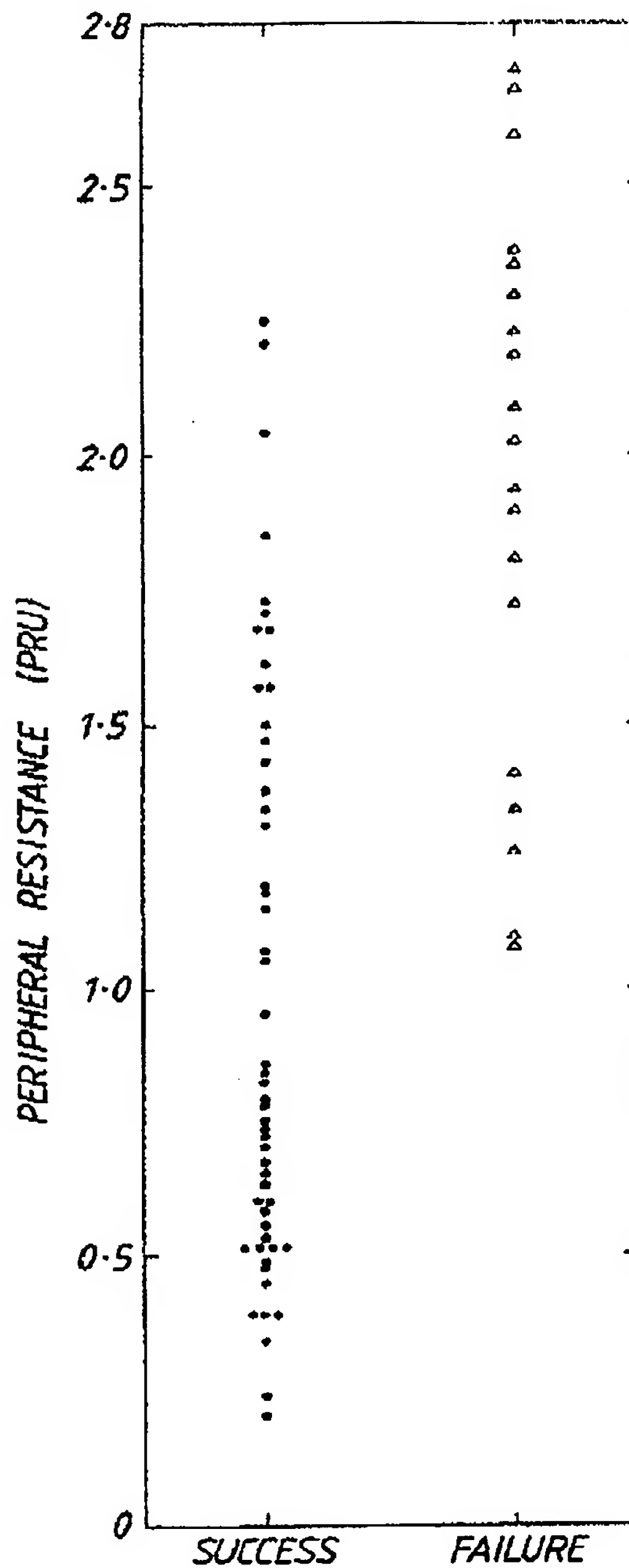


Fig. 7.

PROSTITUTE CLINIC

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